

**II. General Comments**

The undersigned acknowledges a telephone conference with Examiner Wells. During this conference, Examiner Wells clarified that the "Cretois" reference found, e.g., at page 5, line 1 of the outstanding Office Action, refers to *Cretois* (U.S. Pat. No. 5,558,859).

Applicants respectfully request that the Office enter this document on the Notice of References Cited, namely, Form PTO-892; and return a copy with the next Action.

**III. Rejection Under 35 U.S.C. § 112, Second Paragraph**

The Office has rejected claims 1 to 8 and 10 to 29 as indefinite for the reasons set forth beginning at page 2 of the outstanding Office Action. Specifically, the Office argues that these claims "are rejected for the use of improper Markush groups." Office Action at 2, line 19. Applicants respectfully disagree.

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Applicants are their own lexicographers and may define their invention in essentially what ever terms they choose as long as those terms are clear and not contrary with the accepted meaning in the art. *M.P.E.P.* § 2173.01. Here, claim 1, for example, recites alternative language. Such "or" terminology language is *per se* acceptable. *M.P.E.P.* § 2173.05(h), II. As such, Applicants respectfully submit that the present claims meet the requirements of clarity and precision. *M.P.E.P.* § 2173.02. Thus, Applicants respectfully request that this rejection be withdrawn.

**IV. Rejections Under 35 U.S.C. § 103(a)**

The Office rejects claims 1 to 8 and 10 to 29 as allegedly obvious over the combination of *Claussner-509* (U.S. Pat. No. 6,087,509) or *Claussner-553* (U.S. Pat. No. 5,750,553) in view of *Cretois* (U.S. Pat. No. 5,558,859), *Lai* (U.S. Pat. No. 5,916,910), *Ismail* (U.S. Pat. No. 5,541,220), *Galey* (WO 92/21317), *Dumats* (WO 91/19701), and *Estradier* (EP 427 625) for the reasons set forth on pages 3 to 6 of the outstanding Office Action. Applicants respectfully disagree that one of ordinary skill in the art would have been motivated "to have modified the compositions of [*Claussner-509*] or [*Claussner-553*] by the teachings of [*Cretois*] and obtain a composition comprising [a compound of] formula (I), vinylimidazolium methochloride/vinylpyrrolidone copolymer, polyethoxylated hydrogenated castor oil, and solvent" as argued by the Office. Office Action at p. 6, lines 5-7.

Specifically, the Office must show reasons that the skilled artisan, confronted with the same problems as the inventor and lacking knowledge of the claimed invention, would choose the elements from the cited prior art references for combination in the manner claimed. *M.P.E.P.* § 2143.01; see, also *In re Rouffet*, 47 USPQ2d 1453, 1457-8 (Fed. Cir. 1998). Importantly, with respect to this motivation, the Federal Circuit placed the burden on the Office to present "clear and particular" evidence showing motivation to combine. *In re Dembiczak*, 50 USPQ.2d 1614 (Fed. Cir. 1999). Applicants respectfully submit that the Office's motivation is not particular to the presently claimed composition and, as such, that nothing in these references provides the required motivation for the Office's proposed composition

and that the Office failed to meet its burden of establishing a prima facie case of obviousness.

Here, neither *Claussner-509* nor *Claussner-553*, as the Office admits, "teach a copolymer of vinylimidazolium methochloride/vinyl pyrrolidone or polyethoxylated hydrogenated castor oil." Office Action of 11/15/00 at 8, lines 11-12. So, the Office combines the teachings of each reference with those of *Cretois* in an attempt to remedy these deficiencies. *Cretois* states: "In addition to the ceramides and/or glycoceramides and the vinylpyrrolidone polymers defined above, the compositions according to the invention may further contain . . . antiseborrheic agents." Col. 6, lines 36-44.

However, the term "antiseborrheic agents" is not particular to the compounds of either *Claussner-509* or *Claussner-553*. There exists a vast number of possible "antiseborrheic agents" encompassed by this generic term. For example, many types of agents are listed in the *Science of Hair Care*, C. Zviak, Marcel Dekker, Inc. 1986, pp. 469-499 (enclosed for the Office's consideration and convenience) at 490-493. Nothing in *Cretois* motivates one to use any particular "antiseborrheic agents," let alone the particular compounds of either *Claussner* patent.

Also, *Cretois* displays a clear preference for compositions other than those proposed by the Office, because *Cretois* does not teach or suggest either *Claussner-509*'s compounds or *Claussner-553*'s compounds. Moreover, neither *Claussner-509* nor *Claussner-553* displays a clear preference for compositions other than those disclosed, because these references, as the Office admits, do not teach

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*Cretois's* vinylimidazolium-copolymers. So, collectively, the teachings of these references cannot provide the required motivation to use the Office's proposed composition over any other conceivable composition. Thus, there is no motivation to combine the teachings of these references, and the Office has failed to meet its burden in establishing a prima facie case of obviousness over the combination of these references.

Beyond this reason, the *Science of Hair Care* reference actually teaches away from the Office's proposed composition. Specifically, the *Science of Hair Care* states: "[a]ttempts to use topical antiandrogen drugs in humans have been disappointing, in contrast with the findings in rodents" (the *Science of Hair Care* at 490, under Treatment, 2. Hormones). The *Science of Hair Care* hypothesizes that the disappointment may stem from the deeper location of the sebaceous gland in humans from rodents, thus making topical/local treatment ineffective. *Id.* Regardless of the mechanism, if antiandrogen drugs in humans have been disappointing as taught by the *Science of Haircare*, then one of ordinary skill in the art would not have been motivated to use any antiandrogen drug such as *Cretois's* "antiseborrheic agent."

These observations are important, because both *Claussner* patents teach its compounds present anti-androgenic activity: "The products which are a subject of the present invention possess useful pharmacological properties, in particular they fix on the androgen receptor and they present an anti-androgenic activity."

*Claussner-509* at col. 9, line 19-22; see also *Claussner-553* at col. 13, lines 52-55.

Because the compounds of the *Claussner* patents possess anti-androgeneic activity, one of ordinary skill in the art would not have been motivated to use the compounds of either *Claussner-509* or *Claussner-553* as *Cretois*'s "antiseborrhoeic agent" in the Office's proposed composition.

As a result, one of ordinary skill in the art would not have been motivated to make the Office's proposed modification. Because the prior art teaches away from such a combination, there is no motivation to combine the teachings of these pairs of references. See *M.P.E.P.* § 2145 X D. Thus, the Office has failed to meet its burden in establishing a prima facie case of obviousness using the combination of these references.

Turning to the Office's second basis of motivation, Applicants disagree that one of ordinary skill in the art would have been motivated "to have modified the composition of the combined references by the teachings of [*Lai, Ismail, Estradier, Galey, and Dumats*]" as argued by the Office. Office Action at 6, lines 13-15. Nevertheless, the Office does not rely upon any combination of these references to repair the deficiencies of the teachings of *Claussner-509*, *Claussner-553*, and *Cretois*. Merely acknowledging that additives can be added would not direct one of ordinary skill in the art to those of the Office's proposed composition. Thus, none of these references provides the motivation necessary to establish a prima facie case of obviousness. Accordingly, the present rejection should be withdrawn for this reason.


**CONCLUSION**

Applicants respectfully request reconsideration and reexamination of the pending claims. If there are any questions that can be resolved by a telephonic conference, please contact Sean A. Passino at (202) 408-6065.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Enclosures:

*Science of Hair Care*, C. Zviak, Marcel Dekker, Inc. 1986, pp. 469-499.